ZIMMER BIOMET

Your progress. Our promise.™

Thoracolumbar Solutions

TM Ardis®
Interbody System

Surgical Technique Guide

Trabecular Metal™ Technology

TABLE OF CONTENTS

Zimmer Biomet Spine does not practice medicine. This technique was developed in conjunction with health care professionals. This document is intended for surgeons and is not intended for laypersons. Each surgeon should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training surgeons have received. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as the best treatment for each patient. Results will vary based on health, weight, activity and other variables. Not all patients are candidates for this product and/or procedure.

DEVICE DESCRIPTION

The TM Ardis Interbody System is manufactured from Trabecular Metal Material (porous tantalum) and comes in 40 sizes, making it one of the most versatile interbodies in the industry. With this wide range of options, surgeons can ensure a customized fit to varying patient anatomies and can use the implant in a variety of surgical approaches.

Indicated for use as an MIS or open, TLIF or PLIF intervertebral body fusion device with supplemental fixation at one or two levels, the TM Ardis Interbody System is an osteoconductive implant with a minimally invasive, self-distracting design. With a low modulus of elasticity similar to that of subchondral bone, the Trabecular Metal Implant facilitates load-sharing. The TM Ardis System has a high coefficient of friction against cancellous bone to help resist implant migration and expulsion. This allows for a high degree of initial stability. Available in a broad range of sizes, the TM Ardis Interbody System's convex design accommodates varying patient anatomies and features low-profile, anti-glare instrumentation to provide excellent visibility to facilitate easier, more efficient procedures.

TM Ardis Interbody System features:

- Osteoconductive material allows for bony in-growth into the material of the device
- Anatomically shaped implant and self-distracting nose eases implant insertion
- Full range of MIS-compatible instruments designed to facilitate a controlled procedure
- Available in multiple lengths, two widths and 1mm height increments to accommodate differing patient anatomies

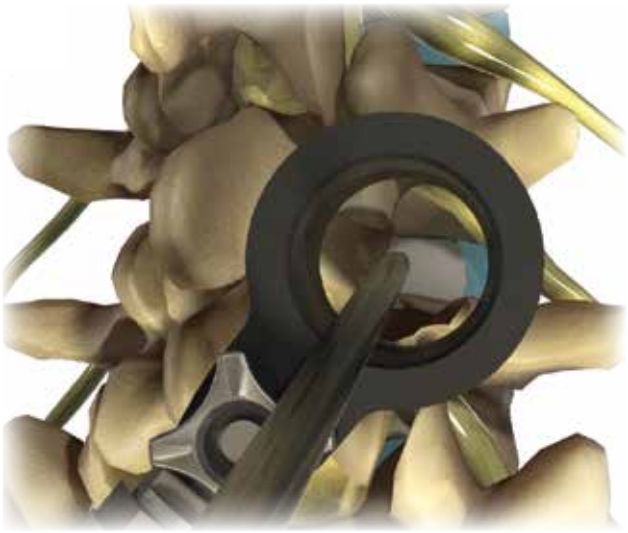
SURGICAL TECHNIQUE: TRANSFORAMINAL LUMBAR INTERBODY FUSION

TLIF: PREPARATION AND ACCESS

STEP 1

Patient Positioning

- Position on radiolucent table with adequate clearance for a fluoroscopic C-arm (for A/P lateral and oblique images of pedicle and vertebral body).
- All other hardware utilized for patient positioning should be checked for radiolucency.

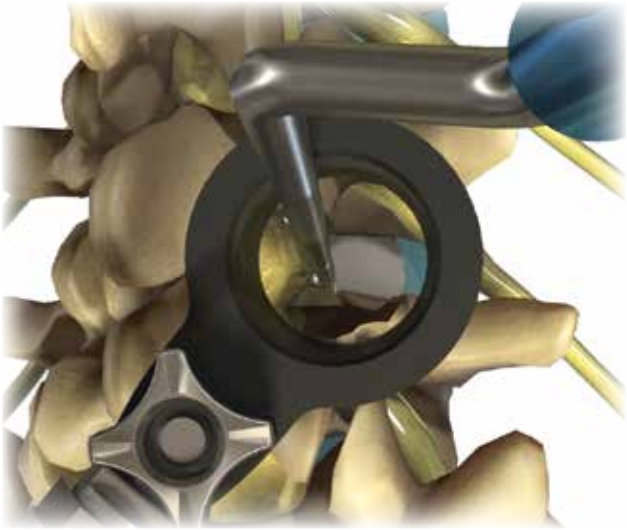


STEP 2

Bony Decompression

- Using **osteotomes** and **Kerrison rongeurs**, remove the facet and portions of the lamina.

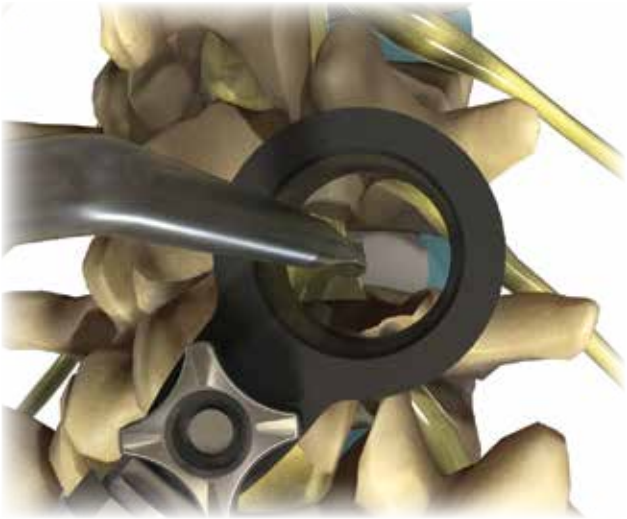
TLIF: PREPARATION AND ACCESS



STEP 3

Ligamentum Flavum

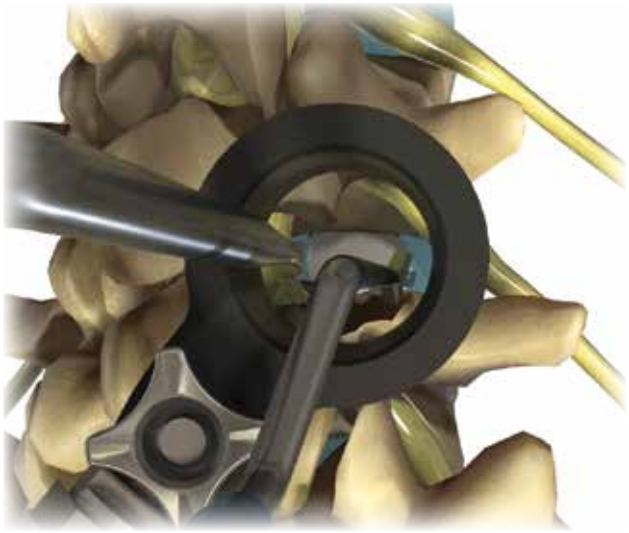
- Remove ligamentum flavum from bony attachments.
- Mobilize with **woodson** or **fine curettes**.
- Control epidural bleeding with bipolar cautery.



STEP 4

Nerve Root, Dura Mobilization

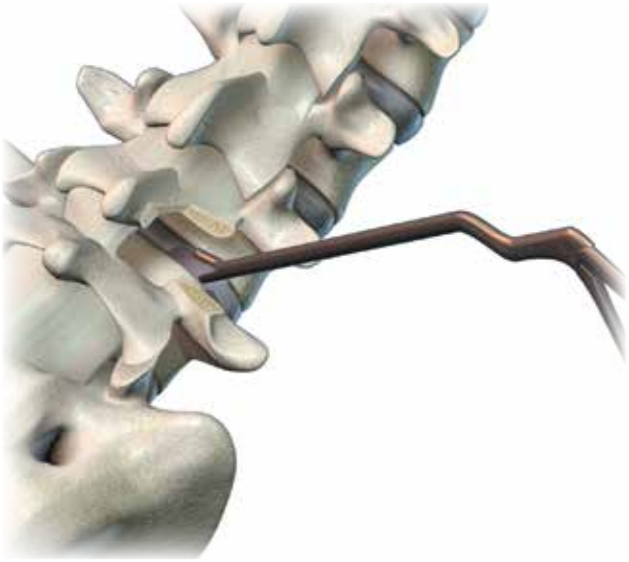
- Mobilize the nerve root and dura from soft tissue; identify bony structures with a **blunt probe**.
- Retract the nerve root and dura.



STEP 5

Annular Window

- Remove blood and soft tissue fragments with a suction catheter; create an annular window with an annulus knife.



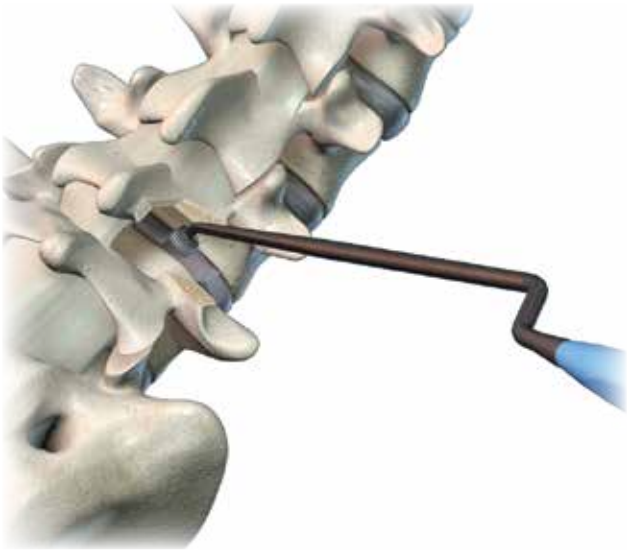
STEP 6

Remove Disc Tissue

- Connect the **cutting distractor** or **shaver** to its respective **T-handle** and insert into the disc space; rotate it to free disc tissue.
- Remove disc fragments with **pituitary rongeurs**.

Note: *The distance from the tip to the laser-marked line on the Ardis shaver indicates the approximate length of a 26mm implant. The distance from its tip to the point where the gold stops indicates the approximate length of a 34mm implant, always be cognizant of the depth of insertion instruments.*

TLIF: PREPARATION AND ACCESS *(continued)*

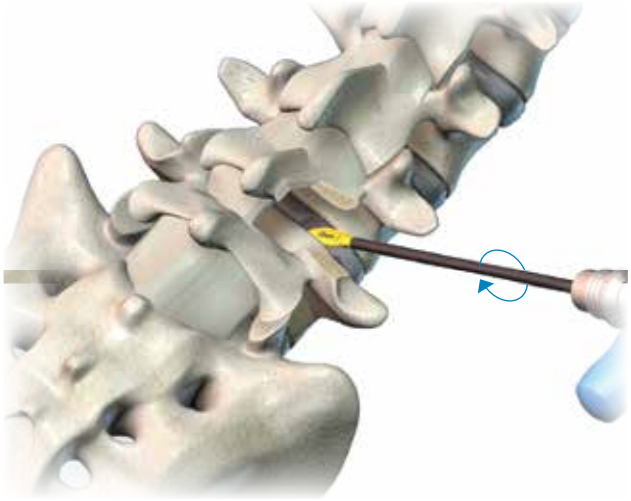


STEP 7

Endplate Preparation

- With osteotomes or Kerrisons, remove osteophytes and the posterior lip of adjacent vertebral bodies if needed.
- Remove remaining endplate cartilage with curettes, **straight rasps** or **angled rasps**.
- Make sure the endplates are well-cleaned to create a surface of bleeding bone in order to maximize bone implant interface.

TLIF: SIZING AND PLACEMENT



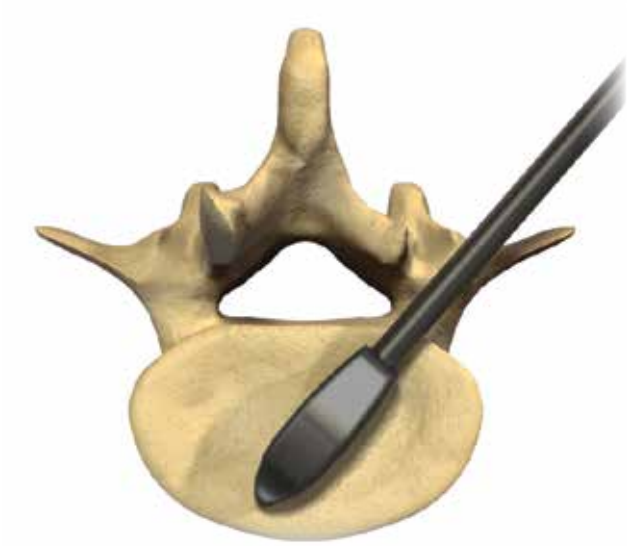
STEP 8

Distraction

- Open the disc space to the desired height.
- Connect a distractor or shaver to its respective T-handle. Insert the instrument into the disc space and rotate its axis, opening the space to a height equal to the distractor or shaver.

  Note: *The distance from the tip to the laser-marked line on the Ardis shaver indicates the approximate length of a 26mm implant. The distance from its tip to the point where the gold stops indicates the approximate length of a 34mm implant.*

  Note: *If additional distraction is desired, distract via the spinous processes or pedicle screws until the desired height is achieved.*



STEP 9

Implant Sizing

- Insert a **trial** into the disc space and view under fluoroscopy to determine the proper implant size. The **slaphammer** can be used to remove the trial if necessary.

TLIF: SIZING AND PLACEMENT *(continued)*

INCORRECT

CORRECT

STEP 10

Final Implant Preparation

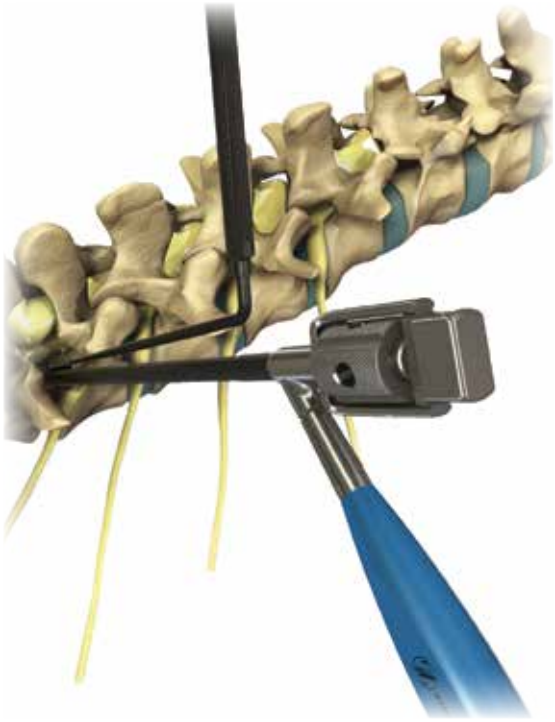
- Select the implant size based on the trial's fit. There is no need to undersize or oversize the implant.
- Attach the implant to the **inserter**.

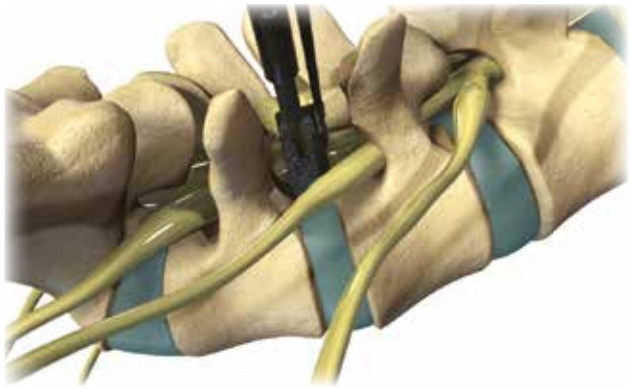
Finger-Tighten Implant to Inserter

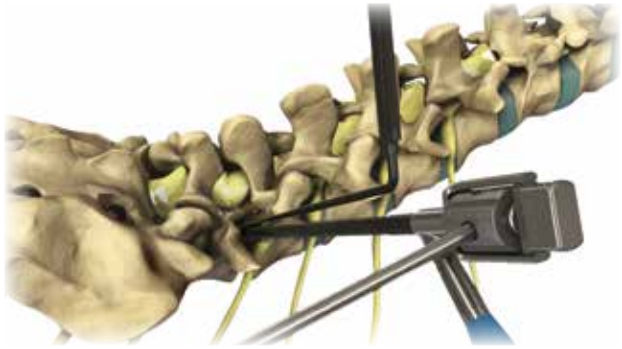
- Ensure the knob is loose by turning it counterclockwise.
- Attach the implant to the inserter by sliding the implant's lateral recesses onto the lateral grasping arms of the inserter. Ensure the implant is fully seated as pictured.
- Once fully seated, turn the knob clockwise until it is finger-tight. The implant should be securely attached to the inserter with no toggle between the implant and inserter. If there is any motion between the implant and inserter, further tighten the knob until the motion is eliminated.

Note: *Do not use the bone tamp to aid in tightening the knob.*

Note: *The illustration marked "incorrect" shows the implant when it is not fully seated on the inserter.*







STEP 11

Implant Insertion

- Insert the implant into the disc space. Nerve root retractors are available for protection of the neural elements. A mallet can be used for insertion.
- Confirm position radiographically and detach the implant from the inserter by turning the knob counterclockwise for approximately five complete revolutions of the knob. If the inserter does not easily release, it may be off-axis. If this is the case, move the inserter laterally slightly and attempt to detach again.

Note: *Nerve root retractors are available in four sizes (8mm, 10mm, 12mm and 16mm) as well as in left and right versions. Use the 8mm retractor if implanting a 7mm or 8mm implant. Use the 10mm retractor if implanting a 9mm or 10mm implant. Use the 12mm retractor if implanting a 11mm or 12mm implant. Use the 16mm retractor if implanting the 13mm, 14mm or 16mm implant.*

Caution: *The nerve root retractors should not enter the disc space.*

Note: *If difficulty loosening the knob is encountered, use the Ardis bone tamp to unlock the inserter knob by mating it with one of the four holes in the knob of the TM Ardis inserter and rotating it counterclockwise until the knob begins to release. The remaining revolutions can be completed by hand.*

Caution: *Care should be taken when inserting the TM Ardis implant into the disc space to avoid damaging anatomy, implants or instruments.*

TLIF: SIZING AND PLACEMENT *(continued)*

STEP 12

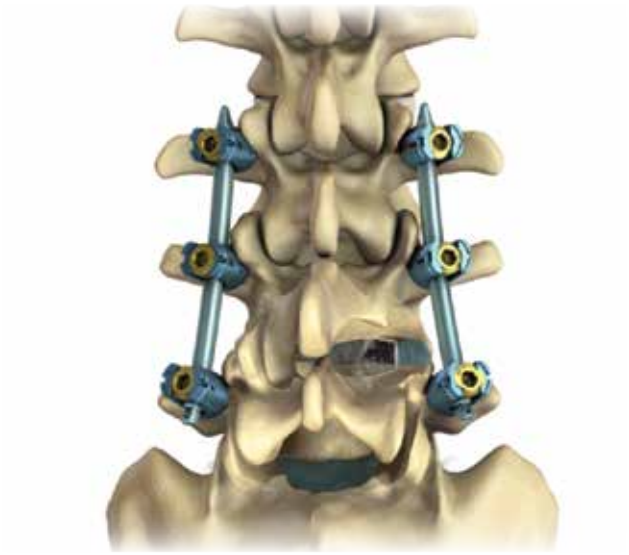
Final Positioning

- Use either the **straight** or **angled tamp** for final implant positioning.
- Mate the tamp with the posterior portion of the implant and mallet the tamp to drive the implant in the desired direction. Autogenous bone graft may be placed around the device.
- After the implant is in its final position, the bone funnel and bone tamp should be used to pack additional autogenous bone graft around the implant.
- Autograft should be packed into the bone funnel, and the bone tamp should be used to push it into the distal end of the funnel and into the disc space.
- The disc space should be filled with autograft on both sides of the implant. Sufficient autograft delivery can be confirmed using fluoroscopy.

STEP 13

Position Confirmation

- Confirm position radiographically.
- Use the bone funnel/bone tamp to pack autogenous bone graft into the disc space around the implant.



STEP 14

Supplemental Fixation

- After the implant is in its final position, add supplemental fixation such as pedicle screws.

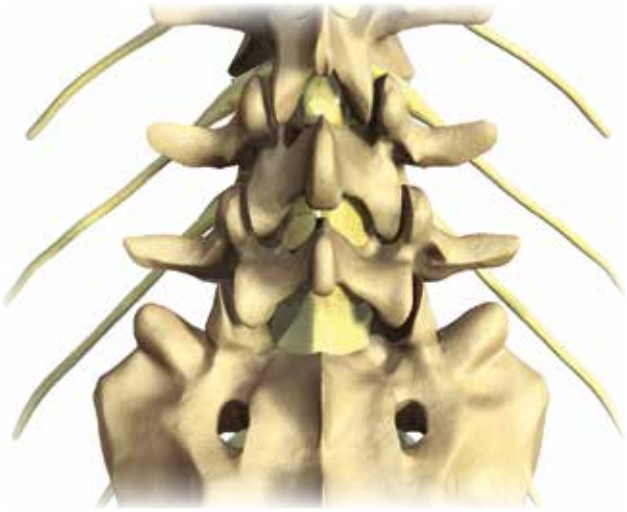
SURGICAL TECHNIQUE: POSTERIOR LUMBAR INTERBODY FUSION

PLIF: PREPARATION AND ACCESS

STEP 1

Patient Positioning

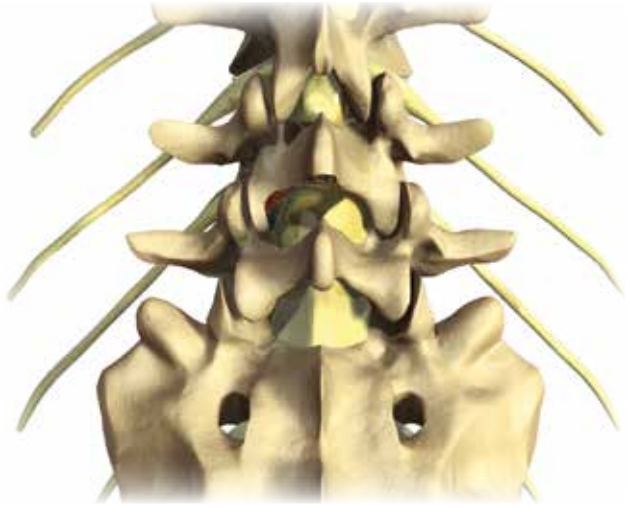
- Position the patient on radiolucent table with adequate clearance for a fluoroscopic C-arm (for A/P, lateral and oblique images of pedicle and vertebral body).
- All other hardware utilized for patient positioning should be checked for radiolucency.



STEP 2

Exposure

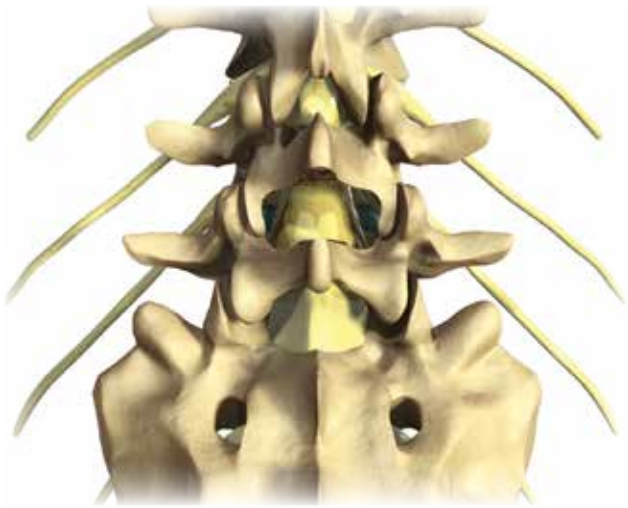
- Obtain A/P and lateral images of the affected level.
- Create a midline incision for the posterior approach.



STEP 3

Bony Decompression

- With osteotomes and Kerrison rongeurs, perform a laminotomy and remove portions of the facet.
- Reduce the need for dura retraction with pedicle-to-pedicle exposure.
- Preserve decorticated bone to pack around implant.

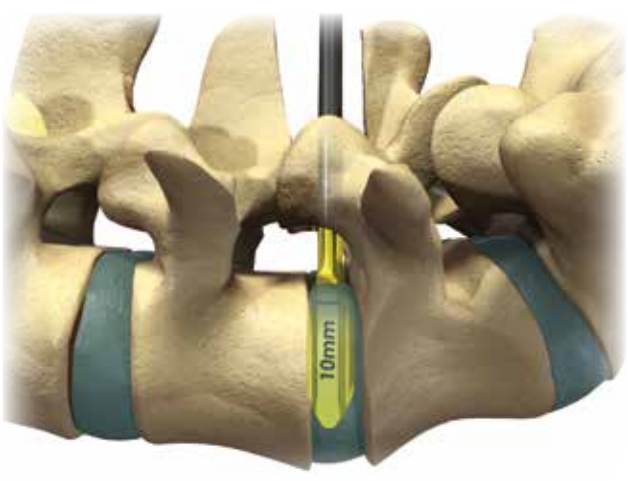


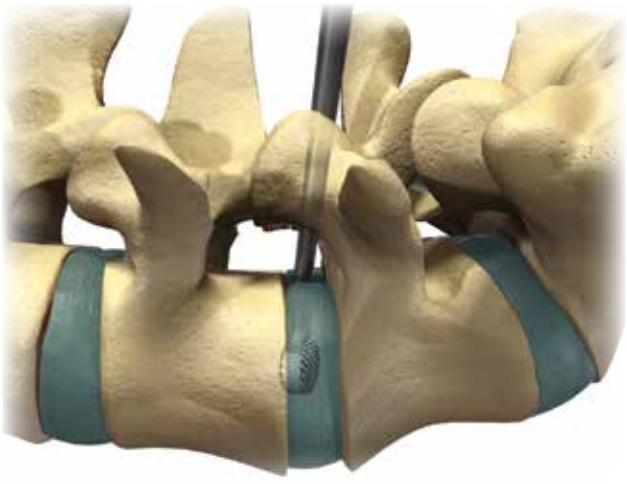
STEP 4

Nerve Root Dura Mobilization

- Using fine curettes or Kerrison rongeurs, remove the ligamentum flavum from the remaining lamina.
- Free dura and nerve roots from surrounding soft tissue.
- Use a bipolar to achieve hemostasis.

PLIF: SIZING AND PLACEMENT





STEP 5

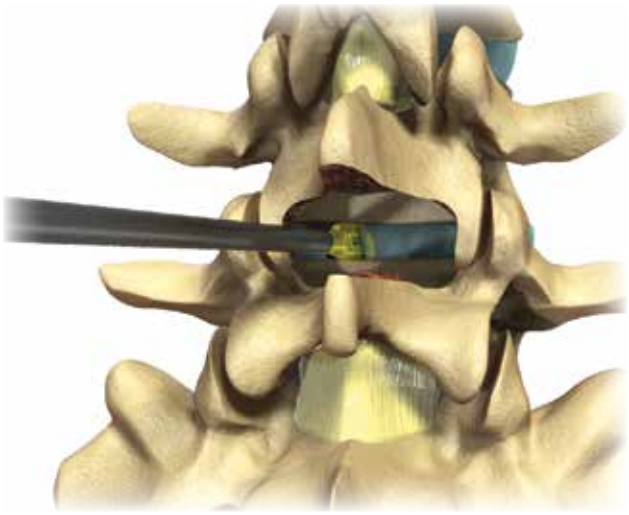
Disc Removal

- Retract the dura and nerve roots and bilaterally incise the annulus.
- Insert cutting distractors into the disc and rotate to free disc tissue.
- Remove disc fragments with pituitary rongeurs.

STEP 6

Endplate Preparation

- With osteotomes, remove osteophytes and the posterior lip of adjacent vertebral bodies.
- Remove remaining endplate cartilage with curettes, straight rasps or angled rasps.
- Make sure the endplates are well-cleaned to create a surface of bleeding bone in order to ensure implant stability.

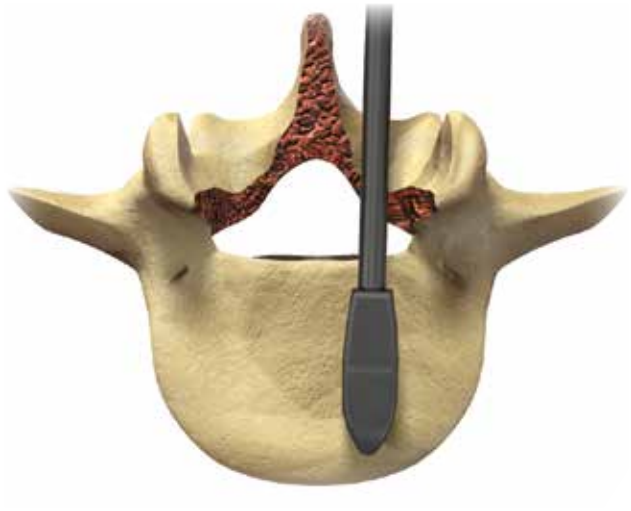


STEP 7

Distraction

- With progressively sized smooth distractors, cutting distractors or shavers, open the disc space to the desired height. Connect a distractor or shaver to its respective T-handle. Insert into the disc space and rotate clockwise and counterclockwise.
- This motion removes the cartilage from the endplates. The shaver is removed and a pituitary rongeur or similar instrument is inserted to remove the scraped cartilage from the disc space. Larger shavers can be used to prepare both endplates simultaneously. Avoid penetration of the shaver through the endplate.

  Note: *The distance from the tip to the laser-marked line on the Ardis shaver indicates that the approximate length of a 26mm implant. The distance from its tip to the point where the gold stops indicates the approximate length of a 34mm implant.*

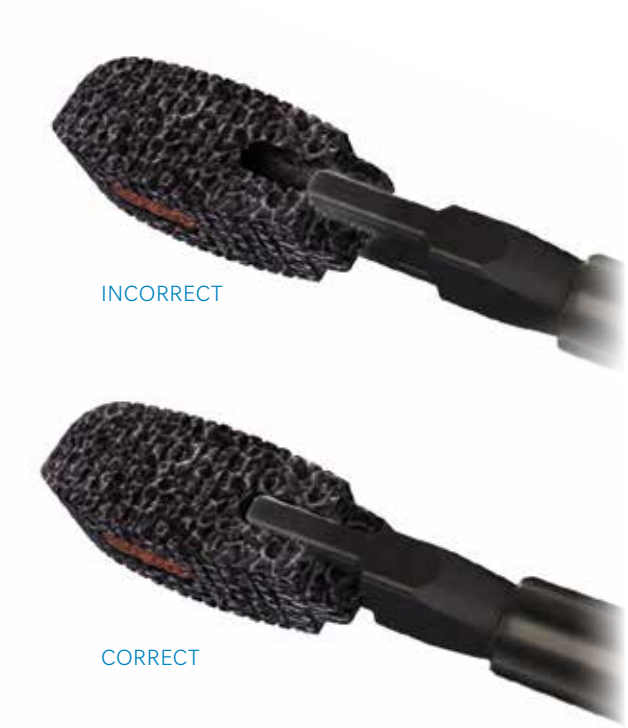


STEP 8

Implant Sizing

- Insert a trial into the disc space and view under fluoroscopy to determine the proper implant size.
- The slaphammer can be used to remove the Ardis trial if necessary.

PLIF: SIZING AND PLACEMENT *(continued)*



STEP 9

Final Implant Preparation

- Select the implant size based on the trial's fit. There is no need to undersize or oversize the implant.
- Attach the implant to inserter.

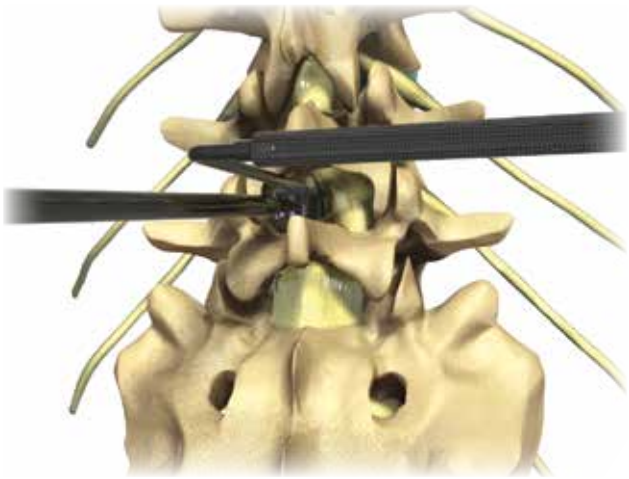
STEP 10

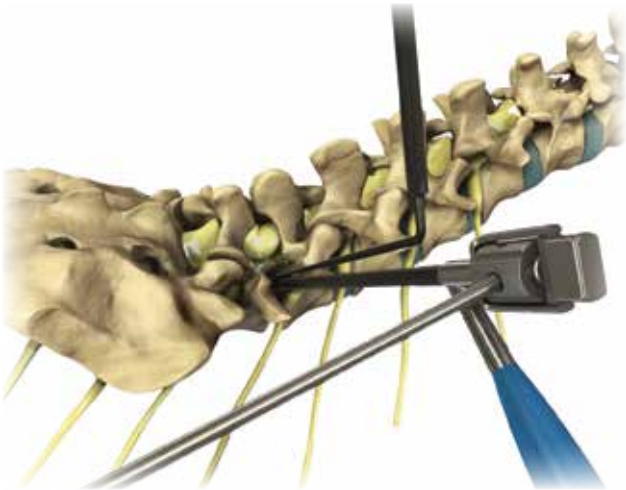
Finger-tighten Implant to Inserter

- Ensure the knob is loose by turning it counterclockwise.
- Attach the implant to the inserter by sliding the implant's lateral recesses onto the lateral grasping arms of the inserter. Ensure the implant is fully seated as pictured.
- Once fully seated, turn the knob clockwise until it is finger-tight. The implant should be securely attached to the inserter with no toggle between the implant and inserter. If there is any motion between the implant and inserter, further tighten the knob until the motion is eliminated.

Note: *Do not use the bone tamp to aid in tightening the knob.*

Note: *The illustration marked as "incorrect" shows the implant when it is not fully seated on the inserter.*





STEP 11

Implant Insertion

- Insert the implant into the disc space. **Nerve root retractors** are available for protection of the neural elements. A mallet can be used for insertion.
- Confirm position radiographically and detach the implant from the inserter by turning the knob counterclockwise for approximately five complete revolutions of the knob.
- If the inserter does not easily release, it may be off-axis. If this is the case, move the inserter laterally slightly and attempt to detach again.

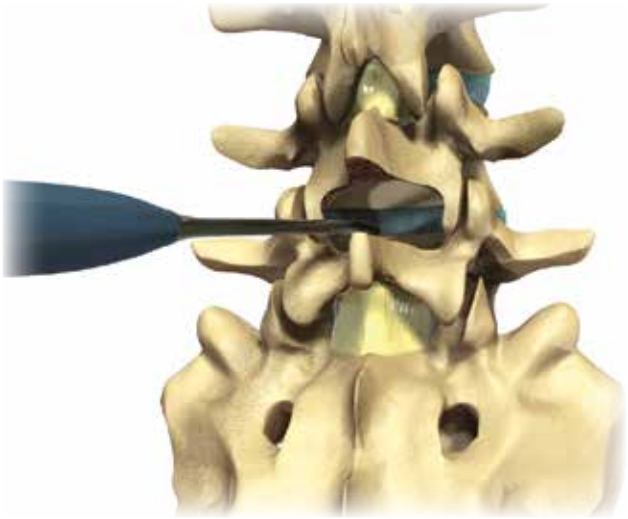
Note: *The nerve root retractors are available in four sizes (8mm, 10mm, 12mm and 16mm) as well as in left and right versions. Use the 8mm retractor if implanting a 7 mm or 8mm implant. Use the 10mm retractor if implanting a 9mm or 10mm implant. Use the 12mm retractor if implanting a 11mm or 12mm implant. Use the 16mm retractor if implanting the 13mm, 14mm or 16mm.*

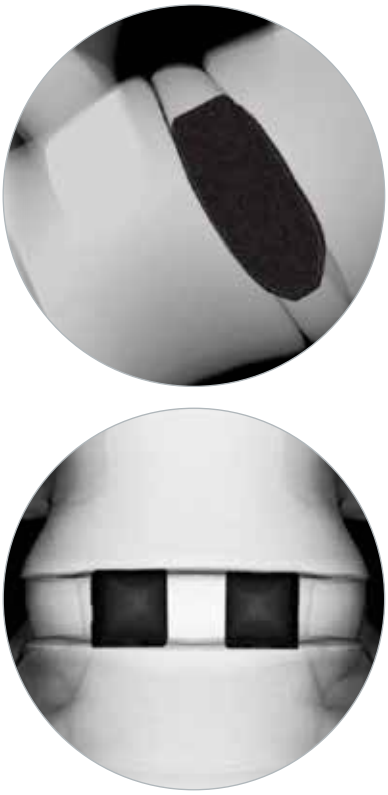
Caution: *The nerve root retractors should not enter the disc space.*

Note: *If difficulty loosening the knob is encountered, use the Ardis bone tamp to unlock the inserter knob by mating it with one of the four holes in the knob of the TM Ardis inserter. Rotate it counterclockwise until the knob begins to release. The remaining revolutions can be completed by hand.*

Caution: *Care should be taken when inserting the TM Ardis implant into the disc space to avoid damaging anatomy, implants or instruments.*

PLIF: SIZING AND PLACEMENT *(continued)*





STEP 12

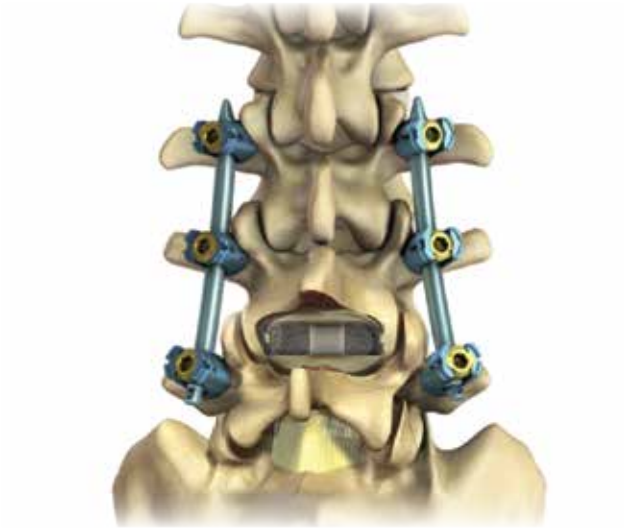
Final Positioning

- Use either the straight or angled tamp for final implant positioning.
- Mate the tamp with the posterior portion of the implant and mallet the tamp to drive the implant in the desired direction. Autogenous bone graft may be placed around the device.
- After the implant is in its final position, the bone funnel and bone tamp should be used to pack additional autogenous bone graft around the implant. Autograft should be packed into the bone funnel, and the bone tamp should be used to push it into the distal end of the funnel and into the disc space. The disc space should be filled with autograft on both sides of the implant.
- Sufficient autograft delivery can be confirmed using fluoroscopy.

STEP 13

Position Confirmation

- Confirm position radiographically.



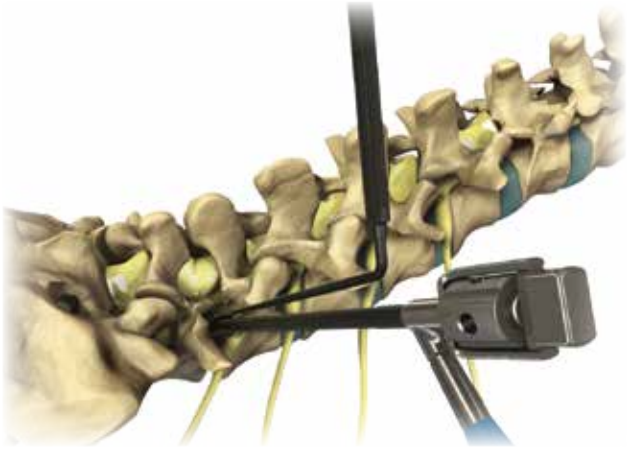
STEP 14

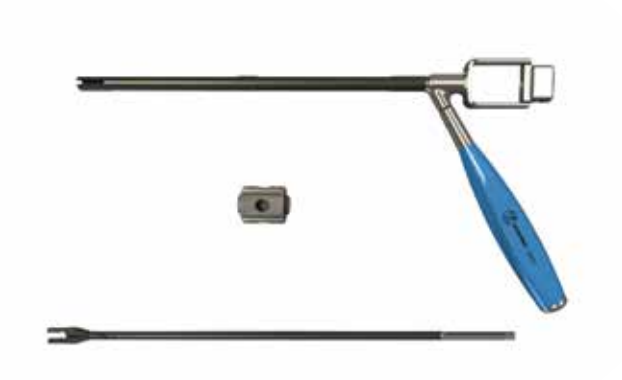
Supplemental Fixation

- After the implant is in its final position, add supplemental fixation such as pedicle screws.

REMOVAL AND REVISION

Should removal or revision of the device be determined necessary early in post-index procedure, it may still be possible to remove the implant via the original approach. Once the healing process has begun, the surgeon may need to consider alternative approaches such as direct anterior or lateral. An osteotome can be used at the interface between the bone and both the superior and inferior faces of the implant to disengage the construct. This effectively cuts the fused column of bone at the level of the interface. Once the implant has been disengaged, the implant can be removed. Use of distraction is suggested to allow easier access to the interface.





INTRAOPERATIVE IMPLANT REMOVAL

- Should removal of the device be required during surgery, the inserter will also serve as an extractor.
- Ensure the knob of the inserter is loose by turning it counterclockwise.
- Once loose, reengage the inserter to the implant by sliding the lateral grasping arms of the inserter into the implant's lateral recesses.
- Once fully seated, turn the knob clockwise to secure the implant to the inserter.
- Connect the slaphammer to the proximal end of the inserter to remove the implant.
- If distraction has been used, be sure to redistract to allow easier removal of the implant.

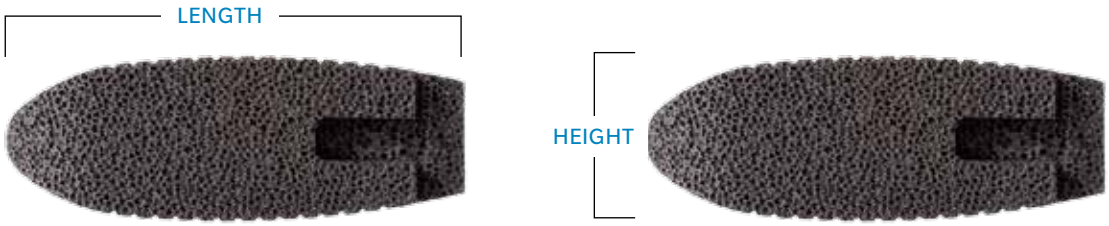
Note: *Once the implant is removed, it should not be inserted, and a new implant should be used.*

INSERTER DISASSEMBLY

- Hold the proximal handle of the inserter and turn the knob counterclockwise until it disassembles from the inserter. This will take approximately 30 revolutions of the knob.
- Pull the distal tip of the inserter to remove the inner shaft from the outer shaft of the inserter.
- Do not disassemble any further.

TM ARDIS IMPLANTS

The implants are available in four lengths (22mm, 26mm, 30mm and 34mm), two widths (9mm and 11mm) and nine heights (7mm–14mm in 1mm increments and 16mm). The height is measured at the tallest point of the device.



9mm Width Implant

LENGTH	HEIGHT
22mm	7mm | 8mm | 9mm | 10mm | 11mm | 12mm | 13mm | 14mm | 16mm
26mm	7mm | 8mm | 9mm | 10mm | 11mm | 12mm | 13mm | 14mm | 16mm
30mm	7mm | 8mm | 9mm | 10mm | 11mm | 12mm | 13mm | 14mm | 16mm

11mm Width Implant

LENGTH	HEIGHT
26mm	7mm | 8mm | 9mm | 10mm | 11mm | 12mm | 13mm | 14mm | 16mm
30mm	7mm | 8mm | 9mm | 10mm | 11mm | 12mm | 13mm | 14mm | 16mm
34mm	7mm | 8mm | 9mm | 10mm | 11mm | 12mm | 13mm | 14mm | 16mm

Trial Sizes

LENGTH	HEIGHT x WIDTH
22mm	7mm x 9mm | 8mm x 9mm | 9mm x 9mm | 10mm x 9mm
26mm	7mm x 9mm | 7mm x 11mm | 8mm x 9mm | 8mm x 11mm | 9mm x 9mm | 9mm x 11mm | 10mm x 9mm | 10mm x 11mm
30mm	7mm x 9mm | 7mm x 11mm | 8mm x 9mm | 8mm x 11mm | 9mm x 9mm | 9mm x 11mm | 10mm x 9mm | 10mm x 11mm
34mm	7mm x 11mm | 8mm x 11mm | 9mm x 11mm | 10mm x 11mm

Trial Sizes

LENGTH	HEIGHT x WIDTH
22mm	11mm x 9mm | 12mm x 9mm | 13mm x 9mm | 14mm x 9mm
26mm	11mm x 9mm | 11mm x 11mm | 12mm x 9mm | 12mm x 11mm | 13mm x 9mm | 13mm x 11mm 14mm x 9mm | 14mm x 11mm | 16mm x 9mm | 16mm x 11mm
30mm	11mm x 9mm | 11mm x 11mm | 12mm x 9mm | 12mm x 11mm | 13mm x 9mm | 13mm x 11mm 14mm x 9mm | 14mm x 11mm | 16mm x 9mm | 16mm x 11mm
34mm	11mm x 11mm | 12mm x 11mm | 13mm x 11mm | 14mm x 11mm | 16mm x 11mm

TM ARDIS INSTRUMENTS

The TM Ardis Interbody System uses the Ardis System's low-profile instrumentation designed to improve visibility and precision. Each instrument has a glare-resistant coating and lengths that are conducive to both MIS and open procedures.

Shavers, 6mm–16mm

DESCRIPTION	PART NUMBER
Incrementally distract the disc space and shave vertebral endplates.	3250-06 – 3250-16

Rasp, Straight

DESCRIPTION	PART NUMBER
Prepares vertebral body endplates by removing cartilage and exposing bleeding bone.	3252-01

Rasp, Curved

DESCRIPTION	PART NUMBER
Prepares vertebral body endplates by clearing cartilage and creating bleeding bone.	3252-02

Ardis Interbody System Trials

DESCRIPTION	PART NUMBER
Utilized to estimate TM Ardis Implant size. Available in 48 sizes, one for each implant size.	3254-series

TM Ardis Inserter

DESCRIPTION	PART NUMBER
Inserts the implant into the disc space.	96-701-10001

Ardis Straight Tamp

DESCRIPTION	PART NUMBER
Advances the implant into its final position.	3258-01

TM ARDIS INSTRUMENTS *(continued)*

Ardis Angled Tamp

DESCRIPTION	PART NUMBER
Advances the implant into its final position.	3258-02

Slaphammer

DESCRIPTION	PART NUMBER
Provides additional force in removal of trials or inserter.	3262-01

T-Handle, 1/4" Square Drive

DESCRIPTION	PART NUMBER
Attaches to shavers for controlled insertion, removal and rotation.	3264-02

Bone Funnel

DESCRIPTION	PART NUMBER
Used to pack autograft material into disc space or implant.	2760-1

Nerve Root Retractor

DESCRIPTION	PART NUMBER
Protects the neural elements.	96-701-20081– 96-701-21161

Bone Tamp

DESCRIPTION	PART NUMBER
Used to pack autograft material into disc space or implant.	2755-1

KIT CONTENTS

*Global Availability: Some instruments and/or implants may not be available in some geographic regions. Check with local representation for product availability.

Ardis Instrument Kit

DESCRIPTION	QUANTITY	PART NUMBER
Ardis Rasp, Straight	1	3252-01
Ardis Rasp, Curved	1	3252-02
Ardis Straight Tamp	1	3258-01
Ardis Angled Tamp	1	3258-02
Ardis Threaded Extractor	1	3260-01
Ardis Inserter	1	3256-01
Bone Funnel	1	2760-1
Bone Tamp	1	2755-1
Ardis Slaphammer	1	3262-01
Ardis T-Handle, 1/4" Square Drive	2	3264-02
Ardis Shaver, 6mm	1	3250-06
Ardis Shaver, 7mm	1	3250-07
Ardis Shaver, 8mm	1	3250-08
Ardis Shaver, 9mm	1	3250-09
Ardis Shaver, 10mm	1	3250-10
Ardis Shaver, 11mm	1	3250-11
Ardis Shaver, 12mm	1	3250-12
Ardis Shaver, 13mm	1	3250-13
Ardis Shaver, 14mm	1	3250-14
Ardis Shaver, 15mm	1	3250-15
Ardis Shaver, 16mm	1	3250-16
Ardis Trial, 7mm x 9mm x 22mm	1	96-701-01071
Ardis Trial, 7mm x 9mm x 26mm	1	96-701-02071
Ardis Trial, 7mm x 9mm x 30mm	1	96-701-03071
Ardis Trial, 7mm x 11mm x 26mm	1	96-701-04071
Ardis Trial, 7mm x 11mm x 30mm	1	96-701-05071
Ardis Trial, 7mm x 11mm x 4mm	1	96-701-06071
Ardis Trial, 8mm x 9mm x 22mm	1	3254-080922
Ardis Trial, 8mm x 9mm x 26mm	1	3254-080926
Ardis Trial, 8mm x 9mm x 30mm	1	3254-080930
Ardis Trial, 8mm x 11mm x 26mm	1	3254-081126
Ardis Trial, 8mm x 11mm x 30mm	1	3254-081130
Ardis Trial, 8mm x 11mm x 34mm	1	3254-081134
Ardis Trial, 9mm x 9mm x 22mm	1	3254-090922
Ardis Trial, 9mm x 9mm x 26mm	1	3254-090926
Ardis Trial, 9mm x 9mm x 30mm	1	3254-090930
Ardis Trial, 9mm x 11mm x 26mm	1	3254-091126
Ardis Trial, 9mm x 11mm x 30mm	1	3254-091130
Ardis Trial, 9mm x 11mm x 34mm	1	3254-091134
Ardis Trial, 10mm x 9mm x 22mm	1	3254-100922
Ardis Trial, 10mm x 9mm x 26mm	1	3254-100926
Ardis Trial, 10mm x 9mm x 30mm	1	3254-100930
Ardis Trial, 10mm x 11mm x 26mm	1	3254-101126
Ardis Trial, 10mm x 11mm x 30mm	1	3254-101130

Ardis Instrument Kit *(continued)*

DESCRIPTION	QUANTITY	PART NUMBER
Ardis Trial, 10mm x 11mm x 34mm	1	3254-101134
Ardis Trial, 11mm x 9mm x 22mm	1	3254-110922
Ardis Trial, 11mm x 9mm x 26mm	1	3254-110926
Ardis Trial, 11mm x 9mm x 30mm	1	3254-110930
Ardis Trial, 11mm x 11mm x 26mm	1	3254-111126
Ardis Trial, 11mm x 11mm x 30mm	1	3254-111130
Ardis Trial, 11mm x 11mm x 34mm	1	3254-111134
Ardis Trial, 12mm x 9mm x 22mm	1	3254-120922
Ardis Trial, 12mm x 9mm x 26mm	1	3254-120926
Ardis Trial, 12mm x 9mm x 30mm	1	3254-120930
Ardis Trial, 12mm x 11mm x 26mm	1	3254-121126
Ardis Trial, 12mm x 11mm x 30mm	1	3254-121130
Ardis Trial, 12mm x 11mm x 34mm	1	3254-121134
Ardis Trial, 13mm x 9mm x 22mm	1	3254-130922
Ardis Trial, 13mm x 9mm x 26mm	1	3254-130926
Ardis Trial, 13mm x 9mm x 30mm	1	3254-130930
Ardis Trial, 13mm x 11mm x 26mm	1	3254-131126
Ardis Trial, 13mm x 11mm x 30mm	1	3254-131130
Ardis Trial, 13mm x 11mm x 34mm	1	3254-131134
Ardis Trial, 14mm x 9mm x 22mm	1	3254-140922
Ardis Trial, 14mm x 9mm x 26mm	1	3254-140926
Ardis Trial, 14mm x 9mm x 30mm	1	3254-140930
Ardis Trial, 14mm x 11mm x 26mm	1	3254-141126
Ardis Trial, 14mm x 11mm x 30mm	1	3254-141130
Ardis Trial, 14mm x 11mm x 34mm	1	3254-141134
Ardis Trial, 16mm x 9mm x 22mm	1	3254-160922
Ardis Trial, 16mm x 9mm x 26mm	1	3254-160926
Ardis Trial, 16mm x 9mm x 30mm	1	3254-160930
Ardis Trial, 16mm x 11mm x 26mm	1	3254-161126
Ardis Trial, 16mm x 11mm x 30mm	1	3254-161130
Ardis Trial, 16mm x 11mm x 34mm	1	3254-161134
TM Ardis Inserter	1	96-701-10001

TM Ardis Implants

22mm Length Implants

DESCRIPTION	QUANTITY	PART NUMBER
TM Ardis Device, 22mm x 9mm x 7mm	2	06-702-01071
TM Ardis Device, 22mm x 9mm x 8mm	2	06-702-01081
TM Ardis Device, 22mm x 9mm x 9mm	2	06-702-01091
TM Ardis Device, 22mm x 9mm x 10mm	2	06-702-01101
TM Ardis Device, 22mm x 9mm x 11mm	2	06-702-01111
TM Ardis Device, 22mm x 9mm x 12mm	2	06-702-01121
TM Ardis Device, 22mm x 9mm x 13mm	2	06-702-01131
TM Ardis Device, 22mm x 9mm x 14mm	2	06-702-01141
TM Ardis Device, 22mm x 9mm x 16mm	2	06-702-01161

26mm Length Implants

DESCRIPTION	QUANTITY	PART NUMBER
TM Ardis Device, 26mm x 9mm x 7mm	2	06-702-02071
TM Ardis Device, 26mm x 9mm x 8mm	2	06-701-02081
TM Ardis Device, 26mm x 9mm x 9mm	2	06-701-02091
TM Ardis Device, 26mm x 9mm x 10mm	2	06-701-02101
TM Ardis Device, 26mm x 9mm x 11mm	2	06-701-02111
TM Ardis Device, 26mm x 9mm x 12mm	2	06-701-02121
TM Ardis Device, 26mm x 9mm x 13mm	2	06-701-02131
TM Ardis Device, 26mm x 9mm x 14mm	2	06-701-02141
TM Ardis Device, 26mm x 9mm x 16mm	2	06-701-02161
TM Ardis Device, 26mm x 11mm x 8mm	2	06-702-04071
TM Ardis Device, 26mm x 11mm x 8mm	2	06-701-04081
TM Ardis Device, 26mm x 11mm x 9mm	2	06-701-04091
TM Ardis Device, 26mm x 11mm x 10mm	2	06-701-04101
TM Ardis Device, 26mm x 11mm x 11mm	2	06-701-04111
TM Ardis Device, 26mm x 11mm x 12mm	2	06-701-04121
TM Ardis Device, 26mm x 11mm x 13mm	2	06-701-04131
TM Ardis Device, 26mm x 11mm x 14mm	2	06-701-04141
TM Ardis Device, 26mm x 11mm x 16mm	2	06-701-04161

TM Ardis Implants *(continued)*

30mm Length Implants

DESCRIPTION	QUANTITY	PART NUMBER
TM Ardis Device, 30mm x 9mm x 7mm	2	06-702-03071
TM Ardis Device, 30mm x 9mm x 8mm	2	06-701-03081
TM Ardis Device, 30mm x 9mm x 9mm	2	06-701-03091
TM Ardis Device, 30mm x 9mm x 10mm	2	06-701-03101
TM Ardis Device, 30mm x 9mm x 11mm	2	06-701-03111
TM Ardis Device, 30mm x 9mm x 12mm	2	06-701-03121
TM Ardis Device, 30mm x 9mm x 13mm	2	06-701-03131
TM Ardis Device, 30mm x 9mm x 14mm	2	06-701-03141
TM Ardis Device, 30mm x 9mm x 16mm	2	06-701-03161
TM Ardis Device, 30mm x 11mm x 7mm	2	06-702-05071
TM Ardis Device, 30mm x 11mm x 8mm	2	06-701-05081
TM Ardis Device, 30mm x 11mm x 9mm	2	06-701-05091
TM Ardis Device, 30mm x 11mm x 10mm	2	06-701-05101
TM Ardis Device, 30mm x 11mm x 11mm	2	06-701-05111
TM Ardis Device, 30mm x 11mm x 12mm	2	06-701-05121
TM Ardis Device, 30mm x 11mm x 13mm	2	06-701-05131
TM Ardis Device, 30mm x 11mm x 14mm	2	06-701-05141
TM Ardis Device, 30mm x 11mm x 16mm	2	06-701-05161

34mm Length Implants

DESCRIPTION	QUANTITY	PART NUMBER
TM Ardis Device, 34mm x 11mm x 7mm	2	06-702-06071
TM Ardis Device, 34mm x 11mm x 8mm	2	06-701-06081
TM Ardis Device, 34mm x 11mm x 9mm	2	06-701-06091
TM Ardis Device, 34mm x 11mm x 10mm	2	06-701-06101
TM Ardis Device, 34mm x 11mm x 11mm	2	06-701-06111
TM Ardis Device, 34mm x 11mm x 12mm	2	06-701-06121
TM Ardis Device, 34mm x 11mm x 13 mm	2	06-701-06131
TM Ardis Device, 34mm x 11mm x 14mm	2	06-701-06141
TM Ardis Device, 34mm x 11mm x 16mm	2	06-701-06161

TM ARDIS NERVE ROOT RETRACTOR KIT

DESCRIPTION	PART NUMBER
TM Ardis 8mm Nerve Root Retractor, Right Hand	96-701-20081
TM Ardis 10mm Nerve Root Retractor,Right Hand	96-701-20101
TM Ardis 12mm Nerve Root Retractor, Right Hand	96-701-20121
TM Ardis 16mm Nerve Root Retractor, Right Hand	96-701-20161
TM Ardis 8mm Nerve Root Retractor, Left Hand	96-701-21081
TM Ardis 10mm Nerve Root Retractor, Left Hand	96-701-21101
TM Ardis 12mm Nerve Root Retractor, Left Hand	96-701-21121
TM Ardis 16mm Nerve Root Retractor, Left Hand	96-701-21161

IMPORTANT INFORMATION ON THE TM ARDIS INTERBODY SYSTEM

Description

The TM Ardis implant is a single device manufactured wholly from Trabecular Metal (porous tantalum) Material, a highly porous, three-dimensional biomaterial designed for biologic fixation. The TM Ardis implant is a convex, straight TLIF or PLIF device for interbody fusion of the anterior column of the spine. TM Ardis is designed for fusion at one or two contiguous levels in the lumbosacral region (L2–S1). The superior and inferior surfaces of the device are textured and convex. The device also has two slots on the posterior end of the device to mate with the insertion instrument. The height is measured at the device's tallest point.

These implants are intended for single use only and must not be reused under any circumstances.

The TM Ardis system contains implants, offered in a variety of cross-sectional geometries and sizes to accommodate different patient anatomy and physician preference, and instrumentation for insertion and neural element protection. Additionally, the TM Ardis System utilizes the Ardis Instrumentation System for site preparation and trialing.

The Ardis instrumentation system (refer to 07.01471.001 for Instructions for Use) is comprised of instruments and perforated instrument cases that are generally comprised of aluminum, stainless steel and/or polymeric materials.

The instrument cases may be multi-layered with various trays, holders and silicone mats to hold surgical instrumentation in place during handling and storage.

The perforated instrument cases allow sterilization of the contents to occur in an FDA-cleared steam autoclave utilizing a sterilization cycle that has been validated by the user for equipment and procedures employed at the user facility. Instrument cases do not provide a sterile barrier and must be used in conjunction with an FDA-cleared sterilization wrap to maintain sterility.

OUS Indications

The TM Ardis Interbody System is indicated for use as an intervertebral body fusion device at one or two contiguous levels in the lumbosacral region (L2–S1) in the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Patients with previous non-fusion spinal surgery at the involved level may be treated with the device. Patients should be skeletally mature and have had six months of non-operative treatment.

The TM Ardis Interbody System is implanted using a posterior or transforaminal approach and is intended to be used singly or in pairs with supplemental fixation.

Contraindications

- Active local infection in or near the operative region.
- Active systemic infection and/or disease.
- Severe osteoporosis or insufficient bone density, which in the medical opinion of the physician precludes surgery or contraindicates instrumentation.
- Known or suspected sensitivity to the implant materials.
- Endocrine or metabolic disorders known to affect osteogenesis (e.g., Paget's disease, renal osteodystrophy, hypothyroidism, etc.).
- Systemic disease that requires the chronic administration of nonsteroidal anti-inflammatory or steroidal drugs.
- Significant mental disorder or condition that could compromise the patient's ability to remember and comply with preoperative and postoperative instructions (e.g., current treatment for a psychiatric/psychosocial disorder, senile dementia, Alzheimer's disease, traumatic head injury, etc.).
- Neuromuscular disorder that would engender unacceptable risk of instability, implant fixation failure or complications in postoperative care. Neuromuscular disorders include spina bifida, cerebral palsy and multiple sclerosis.
- Pregnancy.
- Patients unwilling to follow postoperative instructions.
- Morbid obesity.
- Conditions other than those indicated.
- Prior surgical procedure using the desired operative approach.
- Current metastatic tumors of the vertebrae adjacent to the implant.
- Symptomatic cardiac disease.
- Skeletal immaturity.
- Grossly distorted anatomy.
- Prior fusion at the level(s) to be treated.

Warnings

- Surgery is not always successful. Preoperative symptoms may not be relieved or may worsen. Surgical knowledge of the procedure and the device are important, as is patient selection. Patient compliance is also important. Tobacco and alcohol abuse may lead to unsuccessful results.
- Reuse of a single-use device that has come in contact with blood, bone, tissue or other body fluids may lead to patient or user injury. Possible risks associated with reuse of a single-use device include, but are not limited to, mechanical failure and transmission of infectious agents.
- Appropriate device selection is crucial to obtain proper fit and to decrease the stress placed on the implant.

- Components of competitive spinal systems should not be used with the TM Ardis Device.
- Delayed healing can lead to fracture or breakage of the implants due to increased stress and material fatigue. Patients must be fully informed of all the risks associated with the implant and the importance of following postoperative instructions regarding weight-bearing and activity levels to facilitate proper bone growth and healing.
- Implants must not be modified or otherwise processed in any way.
- Care must be taken to avoid using dissimilar metals in contact with one another, as corrosion may occur. Additional fixation instrumentation that is used to stabilize the affected level must be made of compatible materials, such as titanium or titanium alloy. Corrosion may accelerate metal fatigue and lead to failure of the implant.
- The implant must be handled carefully following the manufacturer's instructions to prevent damage to the implant.
- Once a device has been implanted, it must never be reused. If the package is damaged or opened but the device is not used, or if the expiration date has passed, the device must be returned to Zimmer Biomet. The device must not be resterilized by the end user.
- The surgeon must be familiar with the appropriate technique to implant the supplemental internal fixation and the appropriate hardware.
- Results may be worse with multilevel disease. Supplemental fixation is required. The surgeon should be familiar with fixation techniques and appropriate hardware. Only supplemental fixation made of titanium or titanium alloy should be used with Trabecular Metal Devices.
- MRI Compatibility
  - The patient must be told that implants can affect the results of computer tomography (CT) or magnetic resonance imaging (MRI) scans.
  - The TM Ardis Device has not been evaluated for safety or compatibility in the MR environment.
  - The TM Ardis Device has not been tested for heating or migration in the MR environment.
- Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

Surgeon Precautions

- The implantation of an intervertebral body fusion device should be performed only by experienced spinal surgeons with specific training in the use of this device, because this is a technically demanding procedure presenting a risk of serious injury to the patient.
- The surgeon must have a thorough knowledge of the mechanical and material limitations of surgical implants made of Trabecular Metal Material and be thoroughly familiar with the surgical technique for implanting the TM Ardis Device for the given Indications for Use.
- Based on fatigue testing results, the physician/surgeon should consider the level of implantation, patient weight, patient activity level and other patient conditions, which may impact on the performance of the system.
- The surgeon should be familiar with the various devices and instruments and verify that all are available before beginning the surgery. Additionally, the packaging and implant should be inspected for damage prior to implantation.
- In the event that removal of the implant is considered (e.g., due to loosening, fracture, corrosion or migration of the implant, infection, increased pain, etc.), the risks versus benefits should be carefully weighed. Such events can occur even after healing, especially in more active patients. Appropriate postoperative care must be given following implant removal to avoid further complication.
- The surgeon must be thoroughly familiar with the options for supplemental internal fixation systems and the associated surgical techniques.
- Implants must be fully seated within the inserter prior to use. Care must be taken not to over-tighten the implant-inserter assembly. Additionally, care must be taken not to manipulate the inserter implant interface in a way not recommended by the surgical technique.
- The surgeon must ensure that the implant is properly seated prior to closing of the soft tissue.
- Extreme caution must be used around the spinal cord, nerve roots and blood vessels.

Patient Precautions

- Postoperative care instructions are extremely important and must be followed carefully. Non-compliance with postoperative care instructions could lead to failure of the device and the possibility of additional surgery to remove the device.
- The patient should limit activities that result in heavy lifting until a physician determines solid bony fusion is achieved.
- An orthotic brace may be worn following surgery for support. The attending physician, based upon each patient's clinical progress, will determine whether a brace is appropriate and, if necessary, the length of time the brace is prescribed.
- Non-steroidal anti-inflammatory and steroidal drugs should be avoided for at least 45 days, or as directed by a physician, postoperatively.

Disclaimer: *This document is intended exclusively for physicians and is not intended for laypersons. Information on the products and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or recommendations. Because this information does not purport to constitute any diagnostic or therapeutic statement with regard to any individual medical case, each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice in whole or in part.*

Caution: *Federal (USA) law restricts this device to sale by or on the order of a physician. Rx Only. For product information, including indications, contraindications, warnings, precautions, potential adverse effects and patient counseling information, see the package insert and www.zimmerbiomet.com.*

The CE mark is valid only if it is also printed on the product label.

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